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TO:	FROM:
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ORGANIZATION/FIRM:	DATE:
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RE:
REPLY BRIEF for Serial No. 09/737,185; Filed December 14, 2000; for PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES; Our File No. 2552-011

NOTES/COMMENTS:

Christian E. Carter-Seyboth
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny C. Bowman,et al.
Serial No.: 09/737,185
Filed: December 14, 2000
Confirmation No.: 9139
Examiner: Yelena G. Gakh
Art Unit: 1743
For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF

The Examiner's Answer through page 13 substantially identically repeats the final rejection, which has already been addressed by Appellant's primary Appeal Brief. Accordingly, this Reply Brief addresses the points made in the response section of the Examiner's Answer beginning on page 13.

Section 112, ¶ 2 Issue

As to the rejection of claims under 35 USC Section 112, second paragraph, the Examiner is conflating the standards of Section 112, second paragraph and section 101. Section 112, second paragraph only requires that the claims have enough clarity so that those of ordinary skill in the art can understand the metes and bounds. There is no doubt that the claims are clear enough so that one of ordinary skill in the art can understand those metes and bounds.

The issue of whether the claims define statutory subject matter is an entirely different inquiry. The Examiner bases her rejection on a finding that the recitation of a population of vessels at the locations enumerated in Appellant's claims is to be given no weight, saying that the location of the vessels is not a manufacture. The Examiner cites no authority for her position, and indeed, Counsel has found none in his research. Nor is there valid precedent for the analysis that one ignores words of claims in a section 112 evaluation if, by themselves, they would not constitute patentable subject matter under section 101. The dissection of a claim to

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pick and choose elements that may or may not be statutory subject matter has long been eschewed. *In re Deutsch*, 553 F.2d 689, 693, 1193 U.S.P.Q. 645 (CCCPA 1977).

Of course, appellant does not concede that the location recitations raise a section 101 issue. As the Supreme Court has recognized, Congress chose the expansive language of 35 U.S.C. 101 so as to include "anything under the sun that is made by man" as statutory subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980). Certainly, a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility falls within that expansive definition. What is claimed is a population with members at the recited locations, not the locations themselves.

Instead of being language to be ignored, recitations of the location of elements can be a critical element in determining patentability under section 103. For example, as is well known, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) In *Gordon*, the claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were **located** at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. This Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The Court of Appeals reversed, finding that if the prior art device was turned upside down, it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged. MPEP 2143.01 Hence, whether the inlets were **located** at the top or the bottom was critically important.

In fact, claims have been held invalid for NOT reciting a location. If the specification discloses that a particular location is critical or essential to the practice of the invention, failure to

recite or include that particular location in the claims may provide a basis for a rejection based on the ground that those claims are not supported by an enabling disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In *Mayhew*, the examiner argued that the only mode of operation of the process disclosed in the specification involved the use of a cooling zone at a particular location in the processing cycle. The claims were rejected because they failed to specify either a cooling step or the **location** of the step in the process. The court was convinced that the cooling bath and its **location** were essential, and held that claims which failed to recite the use of a cooling zone, specifically located, were not supported by an enabling disclosure. MPEP 2174.

Similarly, in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) claims to a sectional sofa comprising, inter alia, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the **location** of the control means.

One of the examiner's queries hypothesizes as to what happens as the vessels move from one facility to another, even postulating whether the claim would be "invalid" for a period of time. The case law points out that the claim is sufficient if it describes a state of affairs that does exist at some time, regardless of what may happen thereafter. *Ex part Sudan*, 224 USPQ 614 (PTO Bd. App. 1983) says with regard to the elements of a kit claim, "What happens in the future is thus clearly irrelevant," citing *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

In the first full paragraph on page 14, the Examiner says the pending claims do not recite a unified manufactured product comprising interconnected elements. There is no requirement that the elements be interconnected, and in fact the elements need not be interconnected. Kit claims, for example, have long been patentable. See *In re Venezia*, 530 F. 2d 950, 189 USPQ 149 (CCPA 1976).

In the second full paragraph on page 14, the Examiner cites MPEP Chapter 2106 for the well known proposition that claim language may raise a question as to the limiting effect of a phrase, such as statements of intended use, field of use, "adapted to" or "adapted for" clauses, "wherein" clauses or "whereby" clauses. While "wherein" is used in Appellant's claim, it does not cause any indefiniteness. For example, claim 1 includes the recitation that "wherein each of

the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities." There is nothing indefinite about that and, in fact, it seems to be the only part of the claim that the examiner is giving weight.

In the paragraph bridging pages 14 and 15, the Examiner addressed alleged indefiniteness of claim 18. The Examiner states that she cannot do a search of the method in claim 18 without Appellant specifying the data to be stored on the electronic tags at the vessel distribution facility. In other words, the Examiner is requiring Appellant to limit this claim to some particular data, when there is no statutory basis for that requirement. If any data of any sort whatsoever is stored, and the other features of the claim are present, the claim is infringed. Those of ordinary skill in the art will clearly understand that. (Appellant acknowledges that claim 18 does at one point refer to the data as "data" and elsewhere as "information." Appellant is willing to amend the claim to make that terminology consistent.)

Petrick Rejections

As regards the art rejection over Petrick (US 6,535,129), whether the location recitations are to be given any patentable weight can be determinative. The Examiner entirely relies on not being required to give them weight in order to sustain her position. Thus, it is clear that if the Board agrees with Appellant that those recitations are to be given meaning, the art rejections that rely on Petrick must be reversed. Recall that the Petrick reference is in the case because the Examiner refuses to accept Appellant's Declarations swearing behind Petrick, saying that Appellant and Petrick are claiming the same invention. She reaches that conclusion by disregarding the location limitations of Appellant's claims. There is no public policy served by the Examiner's novel theory. The claims are understandable, so the metes and bounds are understood, and the subject matter of the claims is clearly within *Chakrabarty's* scope.

In the third full paragraph on page 15, continuing through the first full paragraph on page 16, the Examiner apparently tries to comply with the two-way test for determining whether Appellant and Petrick are claiming the same patentable invention, but she is unsuccessful.

In the last full paragraph on page 15, she reaches the conclusion "Petrick's invention would be an obvious modification of Appellant's invention." She points out that Petrick's claim

8 recites establishing a chain of custody. From there she bootstraps that a chain of custody for a biological specimen inherently comprises distributing, transferring, and analyzing the specimen in the containers. Petrick's claim 8 does not mention any of that, not even "biology." The phrase "chain of custody" does not necessarily imply the examiner's phrase which is "distributing, reading, transferring and analyzing the specimen in the container," nor the specificity of appellant's claims. Furthermore, Petrick's claim 8 does not refer to a wireless tag being attached to the container.

Appellant's claim 19 recites providing a population of biomedical specimen vessels each having a wireless electronic memory tag attached to the vessel at a vessel distribution facility, distributing population members including the wireless electronic memory tag attached thereto to a specimen collection facility, and collecting a specimen from a donor in the specimen container at the specimen collection facility. Petrick's claim 8 requires use of both the RFID tag and the form in combination to establish a chain of custody, so Petrick's form is critical. Appellant claims no form.

Appellant's claim 21 goes on to recite the step of transporting the member vessel with the collected specimen from the specimen collection facility to a specimen testing laboratory and storing the results of the analytical test performed on the specimen in the vessel on the electronic memory tag at the specimen testing laboratory. The Examiner finds all that in Petrick's simple phrase "chain of custody?" Recall again the claim is compared to the claim, not claim vs. specification. The Examiner's conclusion that claim 8 of Petrick's patent and Appellant's claim 18 are claiming the same patentable invention is wrong.

Nor would it have been obvious to modify Petrick's claimed invention to arrive at Appellant's claimed invention. Petrick's specification (not its claim) does discuss showing a chain of custody from the collection custodian 54, through an intermediate custodian 56 to the laboratory 52 (Fig. 1). There is no discussion of how the specimen container gets to the collection custodian, so not even Petrick's specification has a vessel distribution facility, much less Petrick's claims.

At column 3, lines 38-55, Petrick emphasizes the importance of the RFID chip 106 being within the chain of custody form 102, to help assure integrity of the chain of custody. The RFID chip is attached to the specimen collection vessel by the collection custodian, so it cannot be

attached at the vessel distribution facility as is the case with Appellant's claimed invention. Petrick emphasizes showing the association of the RFID chip with the form by the fact that the chip's disassociation from the form is to be evident. This relationship of the chip to the form is fundamental to Petrick's chain of custody scheme. This important relationship is a teaching away from appellant's invention, in which the tag is applied to the vessel before it gets to the "collection custodian" (and no form is mentioned), and it is fundamental to Petrick's claimed invention. Thus, appellant's claimed invention could not have been obvious from Petrick's claimed invention. The parties are claiming different inventions.

Examiner's Noted Errors

In the second full paragraph on page 17, the Examiner says that it is impossible not to interpret claims in light of the specification. For example, she says "chain of custody" can be understood only when reading the specification. While it agreed that the claims can be interpreted in light of the specification, it is believed that the Examiner is going so far as to wholesale import limitations from the specification into the claims, essentially comparing appellant's claims to Petrick's specification, which is improper when evaluating if the parties are claiming the same invention.

In the last sentence of the second full paragraph on page 17, the Examiner says something of a non sequitur: "Regarding the business form to which the tag is attached so that its de-association is visible, the Examiner finds that it is notoriously obvious modification of the Appellant's invention, especially since it is much easier to attach the wireless tag to the paper glued to the vessel (container) then directly to a glass or plastic vessel." The attachment of the tag to paper glued to the glass or plastic vessel has nothing to do with making sure the de-association of the tag from the form that is visible. The visibility of the de-association is a critical part of the Petrick invention, but not related to all to Appellant. Appellant's claims do not mention a form, much less one whose disassociation must be visible.

Berney Rejection

The Examiner begins the discussion of the Berney reference (US 5,777,303) at the bottom of page 17. At the top of page 18, the Examiner says "the Appellant's did not explain the

situation, when multiple samples are collected in a plurality of vessels without bearing any information on whose samples these are, and then have wireless electronic tags attached to them in order to transmit the proper information for each sample. The Appellant's did not describe how such an embodiment could be enabled." Later in that same paragraph, the Examiner says "second, as it is already indicated, it is impossible to imagine that the sample is collected in a tube that does not have an electronic tag with the information related to the patient, which means that the tube has to have the tag with the information about the patient written into the label." It is not appellant's duty to supply a response to such hypotheticals, but there are numersous scenarios that come to mind: Perhaps the label on Berney's test tube is paper, perhaps the test tube is handed to the technician with an oral statement of "this is Joe Smith's," or perhaps it was taken from a specific location in a test tube rack that identifies the sample. Or, perhaps there is only one sample and there is no question as to which is which. Berney himself describes the state of the art as "jotting down" and manual transfer to a computer database (Column 1, lines 13-25). Thus, what the Examiner cannot imagine is really quite likely.

At the bottom of page 18, the Examiner says the whole idea of Berney's invention is to move (transport) vessels with collected specimens to the test site with electronic tags bearing information for the patient for proper analysis to be made. Appellant does not get the idea of transport from Berney, and believes that the Examiner is seeing that in Berney because of the benefit of hindsight from knowing Appellant's invention.

Berney's abstract says the label is attached to the test tube with a detachable support, not the sort of affixation used to accompany a specimen collection vessel transported from a distribution facility to a collection site and then to a lab, particularly if a secure chain of custody is important. Figure 1 of Berney illustrates that the tag is held to the test tube in fingers, reinforcing the notion of detachability. Column 2, lines 28-30 of Berney say these are spring-like fingers "allowing a firm fixation of said labels onto the test tube during the time analysis." (emphasis added) At other times (like before the specimen is in the test tube, or at a specimen collection facility) affixation is apparently not important; or at least not mentioned by Berney. There is no teaching or suggestion supporting the examiner's position that Berney suggests Appellant's invention.

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Conclusion:

In conclusion, the Examiner has erred in numerous ways, as outlined above. Fundamentally, the Examiner disregards the material recitations of the locations of the various members of populations of vessels. Those are not arbitrary locations, but are there because of the progression of the members of the population from one location to the other during processing. Once the locations are given their proper weight, it is clear that Appellant and Petrick are not claiming the same invention, so that Appellant can successfully swear behind Petrick. Moreover, the Berney reference teaches only the use of a tag within a laboratory, and not among the various facilities of Appellant's invention. All of the rejections should be reversed and the claims allowed.

Respectfully submitted,

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